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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____ **COMPLAINT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, brings this action against defendants, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., for patent infringement and alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 United States Code, arising from Barr Laboratories, Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's THALOMID® prior to the expiration of certain patents owned by Celgene that cover that product's use, i.e.,

United States Patent Nos. 6,045,501 (the '501 patent"), 6,315,720 ("the '720 patent"), 6,561,976 ("the '976 patent"), 6,561,977 ("the '977 patent"), 6,755,784 ("the '784 patent"), 6,869,399 ("the '399 patent"), and 7,141,018 ("the '018 patent") (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, defendant Barr Laboratories, Inc. is a corporation having a principal place of business at 223 Quaker Road, Pomona, New York 10970.

4. On information and belief, defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

5. On information and belief, defendant Barr Laboratories, Inc. is a subsidiary of defendant Barr Pharmaceuticals, Inc.

6. On information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are registered to do business in New Jersey. Further, on information and belief, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. maintain executive offices and a manufacturing facility and otherwise transact business within this District.

7. On information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Barr Pharmaceuticals, Inc.

8. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are referred to hereinafter, collectively, as "Barr."

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 2201 and 2202.

10. This Court has personal jurisdiction over Barr by virtue of the fact that Barr has availed itself of the laws of New Jersey and conducts business in New Jersey.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents in Suit

12. On April 4, 2000, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '501 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '501 patent is attached hereto as Exhibit A.

13. On November 13, 2001, the USPTO duly and lawfully issued the '720 patent, entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '720 patent is attached hereto as Exhibit B.

14. On May 13, 2003, the USPTO duly and lawfully issued the '976 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other

Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '976 patent is attached hereto as Exhibit C.

15. On May 13, 2003, the USPTO duly and lawfully issued the '977 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '977 patent is attached hereto as Exhibit D.

16. On June 29, 2004, the USPTO duly and lawfully issued the '784 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On May 3, 2005, a certificate of correction was granted by the USPTO to correct a typographical error in claim 29 of the '784 patent. A copy of the '784 patent and its certificate of correction is attached hereto as Exhibit E.

17. On March 22, 2005, the USPTO duly and lawfully issued the '399 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On March 7, 2006, a certificate of correction was granted by the USPTO to correct typographical errors in claim 19 of the '399 patent. A copy of the '399 patent and its certificate of correction is attached hereto as Exhibit F.

18. On November 28, 2006, the USPTO duly and lawfully issued the '018 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '018 patent is attached hereto as Exhibit G.

The THALOMID® Drug Product

19. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a) for thalidomide capsules (NDA No. 20-785), which it sells under the trade name THALOMID®. The claims of the '501, '720, '976, '977, '784, '399 and '018 patents cover, *inter alia*, methods of use and delivery of pharmaceutical compositions containing the drug thalidomide.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '501, '720, '976, '977, '784, '399 and '018 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to THALOMID®.

Acts Giving Rise to this Suit

21. Pursuant to Section 505 of the FFDCA, Barr filed an ANDA for thalidomide capsules, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules 50 mg, 100 mg and 200 mg ("Barr's Proposed Products"), before the patents-in-suit expire. The Barr ANDA number is 78-505.

22. In connection with the filing of its ANDA as described in the preceding paragraph, Barr has provided written certification to the FDA, as called for by Section 505 of the FFDCA, which alleges that the claims of the '501, '720, '976, '977, '784, '399 and '018 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Barr's ANDA.

23. No earlier than December 6, 2006, Barr sent written notice of its ANDA filing to Celgene. The notice alleged that the claims of the '501, '720, '976, '977, '784, '399, and '018

patents are invalid, unenforceable, and/or will not be infringed by Barr. Barr's notice also informed Celgene that Barr seeks approval to market Barr's Proposed Products before the patents-in-suit expire.

24. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Celgene's receipt of Barr's notice.

Count I: Barr's Filing of the ANDA Infringes the '501 Patent

25. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

26. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '501 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. There is a justiciable controversy between the parties hereto as to infringement of the '501 patent.

28. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '501 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

29. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '501 patent is not enjoined.

30. Celgene does not have an adequate remedy at law.

31. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count II: Barr's Filing of the ANDA Infringes the '720 Patent

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-31 as though fully set forth herein.

33. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '720 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

34. There is a justiciable controversy between the parties hereto as to infringement of the '720 patent.

35. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '720 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

36. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '720 patent is not enjoined.

37. Celgene does not have an adequate remedy at law.

38. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count III: Barr's Filing of the ANDA Infringes the '976 Patent

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as though fully set forth herein.

40. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

41. There is a justiciable controversy between the parties hereto as to infringement of the '976 patent.

42. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '976 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

43. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '976 patent is not enjoined.

44. Celgene does not have an adequate remedy at law.

45. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count IV: Barr's Filing of the ANDA Infringes the '977 Patent

46. Plaintiffs repeat and reallege the allegations of paragraphs 1-45 as though fully set forth herein.

47. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '977 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

48. There is a justiciable controversy between the parties hereto as to infringement of the '977 patent.

49. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '977 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

50. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '977 patent is not enjoined.

51. Celgene does not have an adequate remedy at law.

52. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count V: Barr's Filing of the ANDA Infringes the '784 Patent

53. Plaintiffs repeat and reallege the allegations of paragraphs 1-52 as though fully set forth herein.

54. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '784 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

55. There is a justiciable controversy between the parties hereto as to infringement of the '784 patent.

56. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '784 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

57. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '784 patent is not enjoined.

58. Celgene does not have an adequate remedy at law.

59. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count VI: Barr's Filing of the ANDA Infringes the '399 Patent

60. Plaintiffs repeat and reallege the allegations of paragraphs 1-59 as though fully set forth herein.

61. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '399 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

62. There is a justiciable controversy between the parties hereto as to infringement of the '399 patent.

63. Unless enjoined by this Court, Barr, upon FDA approval of Barr's ANDA, will infringe the '399 patent by making, using, offering to sell, importing, and selling Barr's Proposed Products in the United States.

64. Celgene will be substantially and irreparably damaged and harmed if Barr's infringement of the '399 patent is not enjoined.

65. Celgene does not have an adequate remedy at law.

66. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

Count VII: Barr's Filing of the ANDA Infringes the '018 Patent

67. Plaintiffs repeat and reallege the allegations of paragraphs 1-66 as though fully set forth herein.

68. Barr's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of thalidomide capsules, prior to the expiration of the '018 patent, constitutes infringement of one or more of the claims of that patent as issued under 35 U.S.C. § 271(e)(2)(A).

69. There is a justiciable controversy between the parties hereto as to infringement of the ‘018 patent.

70. Unless enjoined by this Court, Barr, upon FDA approval of Barr’s ANDA, will infringe the ‘018 patent by making, using, offering to sell, importing, and selling Barr’s Proposed Products in the United States.

71. Celgene will be substantially and irreparably damaged and harmed if Barr’s infringement of the ‘018 patent is not enjoined.

72. Celgene does not have an adequate remedy at law.

73. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorney’s fees under 35 U.S.C. § 285.

Count VIII: Inducing Infringement

74. Plaintiffs repeat and reallege the allegations of paragraphs 1-73 as though fully set forth herein.

75. Upon information and belief, Barr Pharmaceuticals, Inc. has infringed the ‘501, ’720, ‘976, ‘977, ‘784, ‘399, and ‘018 patents under 35 U.S.C. § 271(b) by actively inducing Barr Laboratories, Inc. to infringe the ‘501, ’720, ‘976, ‘977, ‘784, ‘399, and ‘018 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene Corporation respectfully requests the following relief:

(A) A judgment be entered that Defendants have infringed the ‘501, ’720, ‘976, ‘977, ‘784, ‘399, and ‘018 patents by submitting the aforementioned ANDA;

(B) A judgment be entered that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Barr's Proposed Products will infringe one or more claims of the '501, '720, '976, '977, '784, '399, and '018 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 78-505 be a date which is not earlier than the later of the expiration of the '501, '720, '976, '977, '784, '399, and/or '018 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Barr's Proposed Products until after the expiration of the '501, '720, '976, '977, '784, '399, and/or '018 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the '501, '720, '976, '977, '784, '399, and/or '018 patents, or from actively inducing or contributing to the infringement of the '501, '720, '976, '977, '784, '399, and/or '018 patents until after their expiration, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Barr's Proposed Products will directly infringe or induce and/or contribute to infringement of the '501, '720, '976, '977, '784, '399, and/or '018 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(G) To the extent that Defendants have committed any acts with respect to the methods claimed in the '501, '720, '976, '977, '784, '399, and '018 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Barr's Proposed Products prior to the expiration of the '501, '720, '976, '977, '784, '399, and '018 patents, a judgment awarding damages to Plaintiff resulting from such infringement together with interest;

(I) Attorney's fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: January 18, 2007

By: _____

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 18, 2007

By: _____

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